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PRESS RELEASE

BOSTON SCIENTIFIC AGREES TO PAY $74 MILLION TO RESOLVE ALLEGATIONS THAT IT SHIPPED ADULTERATED AND MISBRANDED MEDICAL DEVICES

Boston, MA... Natick-based **BOSTON SCIENTIFIC CORPORATION, INC.** has agreed to pay $74 million to the United States to resolve an ongoing investigation concerning its 1998 distribution and subsequent recall of one of its coronary stent delivery systems.

United States Attorney Michael J. Sullivan; Peter D. Keisler, Assistant Attorney General of the U.S. Department of Justice's Civil Division; Margaret O'K. Glavin, Associate Commissioner for Regulatory Affairs, U.S Food and Drug Administration; and Kenneth W. Kaiser, Special Agent in Charge of the Federal Bureau of Investigation in New England, announced today that a civil complaint was filed in federal district court charging **BOSTON SCIENTIFIC CORPORATION, INC.** with distributing in interstate commerce 34,589 medical devices that were adulterated and misbranded between August 12, 1998 through October 5, 1998. To resolve the allegations in the civil complaint, **BOSTON SCIENTIFIC**, without admitting liability, has agreed to pay $74 million to the United States.

The civil complaint alleges that **BOSTON SCIENTIFIC** commercially distributed premounted coronary stents that had a manufacturing defect that resulted in random failures of the balloons used to deploy the stents; that **BOSTON SCIENTIFIC** failed to identify and segregate the defective devices to ensure that they were not distributed commercially; and that **BOSTON SCIENTIFIC** failed to establish proper internal procedures to identify the causes of the defects.

"This case represents a failure by Boston Scientific to take the most appropriate steps in a timely manner to ensure that the devices it was distributing to hospitals nationwide performed properly," said U.S. Attorney Michael J. Sullivan. "The company identified the problem through its own internal testing and took a risk that those same problems would not occur in the marketplace. This type of behavior by a major medical device manufacturer is unacceptable."

Assistant Attorney General Peter D. Keisler stated, "Before engaging in commercial distribution of medical devices, companies that distribute such products bear the responsibility of ensuring that the devices will perform properly. Similarly, when problems arise, the companies bear

an affirmative responsibility to protect consumers and ensure that defective devices do not reach the marketplace."

"Today's actions show that we and the U.S. Department of Justice will vigorously enforce the laws that ensure safe and effective devices," said Margaret O'K. Glavin, Associate Commissioner for Regulatory Affairs at the FDA. "This successful outcome should send a clear signal that device companies, and the other industries FDA regulates, must take all necessary steps to market only products that meet our high standards. The American people demand and deserve no less."

"This is an example where a corporation made a poor business decision and did not sufficiently take into account its obligation to protect against the distribution of defective products," stated FBI Special Agent in Charge Kaiser.

The civil complaint concerns **BOSTON SCIENTIFIC**'s 1998 distribution of a premounted coronary stent delivery system called the NIR™ ON™ Ranger™ with SOX, which was sold to hospital catheterization laboratories throughout the country. According to the civil complaint, the stent system was used by cardiologists in connection with a procedure to clear coronary artery blockages known as percutaneous transluminal coronary angioplasty. The system consisted of a stainless steel mesh sheath called a "stent" mounted on a balloon catheter. Physicians used the balloon catheter to deliver the stent to the proper location in a patient's artery. Once in the proper location, the stent was expanded by inflating the balloon with high pressure bursts of saline solution, which simultaneously expanded the diameter of the stent. Once the stent was deployed, the physician would then deflate the balloon and withdraw the catheter leaving the stent in the artery wall to provide arterial support and prevent reclosure of the artery.

The civil complaint filed by the United States concerns the "delivery system" used to deploy the stents and makes no allegations or suggestion that the stents actually placed within patients were defective or otherwise presented a risk of harm to patients.

As U.S. Attorney Sullivan explained, "This case does not involve any risk to those patients who had one of these stents implanted in their bodies. The issue is not, and was never, whether the stent performed properly. Rather, the issues raised in the complaint concern the functioning of the balloon used to deploy the stent in the NIR™ ON™ Ranger™ with SOX device, the fact that the balloon failed to perform at the pressures indicated on the devices' labels, and the fact that **BOSTON SCIENTIFIC**, while undertaking an internal investigation and consulting with outside regulatory counsel, did not take sufficient steps to ensure that these devices never reached the marketplace."

According to the complaint, Boston Scientific began shipping the NIR™ ON™ Ranger™ with SOX device on August 12, 1998. Within days, the company began receiving reports from hospitals that the balloons that were used to deploy the stents in the patients' bodies were prematurely failing by leaking or bursting at pressures below the maximum pressures stated on the device labels. Such failures potentially could allow the pressurized saline solution used to inflate the balloon to spray out of the balloon and cause tears in the walls of the patients' arteries. On August 28, 1998, engineers at **BOSTON SCIENTIFIC**'s Scimed subsidiary conducted an internal investigation to determine the extent of any problem or defect in the devices that were in the company's finished goods inventory and awaiting shipment. Preliminary test results conducted on the most popular size of the device

revealed that 19 of 90 (21.1%) of the devices tested had balloons that were failing prematurely. As a direct result of this dramatic and unexpected level of failures, the engineers immediately shut down manufacture of that size device and forwarded the test results to corporate management. By August 30, 1998, internal testing of devices pulled from finished goods inventory was completed. The testing confirmed the preliminary results and showed that the balloons were failing prematurely at rates between 2.9% and 12.6% depending upon the size of the device. As a result, the engineers shut down manufacturing of the entire NIR™ ON™ Ranger™ with SOX product line and communicated the test results to corporate management. At that point in time, the decision whether to continue shipping the devices became the responsibility of **BOSTON SCIENTIFIC** corporate management.

The complaint alleges that on September 2, 1998, **BOSTON SCIENTIFIC** convened an internal Field Action Committee to review the situation and determine whether the company should continue shipping the device. As of that date, the company had received only 39 complaints relating to premature balloon failures out of estimated 6,500 devices used and had received reports of 4 devices causing patient injury or complications. The Field Action Committee concluded that commercial distribution should continue.

Thereafter, **BOSTON SCIENTIFIC** continued its internal investigations as to the balloon problems, but was unable to determine the root cause and was unable to develop a screening test to be used during manufacturing to identify those devices with balloons that would fail. The company was also unable to develop a screening mechanism to segregate those defective devices already in finished goods inventory awaiting commercial distribution. Despite this inability to solve the problem and identify defective devices, the company, after consulting with outside counsel and with a leading cardiologist, continued commercial shipments.

Additional internal testing completed by mid-September confirmed that the devices continued to be plagued with failing balloons. On September 17, 1998, in a phone conversation, a management employee at **BOSTON SCIENTIFIC** described the situation the company faced. "[W]e have this embedded problem in our inventory and in our current manufacturing process... and that we are producing product that does not meet the label spec or does not meet the standard - uh- against which this product was reviewed and approved. So even though, even though the outcome in the market is very, very good - in fact better than our competitors - uh, we're agonizing over this because, in spite of that, we still find ourselves in a situation where we're in violation of the Code and we're in fact shipping adulterated product and we cannot do that." Ultimately, **BOSTON SCIENTIFIC**, after again discussing the issue with outside counsel and a cardiologist, decided to continue shipping the stent system and consult with the FDA about the ongoing problem with the device.

Within days, representatives from **BOSTON SCIENTIFIC** participated in a conference call with representatives from the FDA. During this call, the parties discussed various matters pertaining to the stent system including the fact that **BOSTON SCIENTIFIC** was continuing to ship the device despite not knowing the cause of the problem or having developed a test procedure to screen for defective devices. Thereafter, despite two separate conversations with an FDA representative who advised a **BOSTON SCIENTIFIC** management employee that the FDA had serious concerns about the company's continued shipments of the stent system, **BOSTON SCIENTIFIC** continued shipping the devices through October 5, 1998 after which it commenced a nationwide recall of its NIR™ ON™ Ranger™ with SOX device.

The case was investigated by the U.S. Food and Drug Administration and the Federal Bureau of Investigation. It is being prosecuted by First Assistant U.S. Attorney Michael K. Loucks, Assistant U.S. Attorney James E. Arnold, Deputy Chief of Sullivan's Health Care Fraud Unit, Assistant U.S. Attorney Anton P. Giedt in Sullivan's Civil Division, Assistant U.S. Attorney James J. McGovern in Sullivan's Criminal Division and Eugene M. Thirolf, Director of the U.S. Department of Justice's Office of Consumer Litigation.

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